

REMARKS

Reconsideration of this application, and allowance of the claims is respectfully requested.

The amendment to the specification is to correct an obvious, clerical error.

The examiner is urged to note that the PTO 892 form which carries a single reference, Atkinson et al., 5,501,426, was returned to applicant's attorney with the last office action, but not initialed. While it is obvious that the examiner has considered Atkinson et al. '426, since it is the patent on which the rejection is based, a signed copy of the PTO 892 form is requested, to be sure that the reference appears in the U.S. patent documents cited on the face of the patent when it issues.

The examiner has rejected claims 1-22 as indefinite, the language in question being "... being essentially free of longitudinally inwardly extending projections" as found in claims 1 and 9.

It is believed that the specification makes clear what is being referred to.

As found on page 5, within the second, complete paragraph, note the following language: "With such a seal being inside of the elastomeric wall, a simplified elastomeric wall can be used without major, extending skirts or other appendages as in much of the prior art, while such an elastomeric wall can be swabbed for aseptic cleaning, and good, reliable sealing and retention between the male luer and the medical device can still be achieved."

Turning to the bridging paragraph of pages 11 and 12, note the quotation: "It can be seen that such an elastomeric wall is wider than it is long, and, like the previous embodiments, it lacks long projections, skirts, or appendages which extend downwardly into bore portion 32b. Such projections, skirts and appendages in certain analogous

prior art devices operate in conjunction with a tube that is advanced into such systems. By the elimination of these, a simplification of manufacture and reduction of cost is achieved".

From this supporting language, it is believed that the language of the claims: "... being essentially free of longitudinally inwardly extending projections..." is clarified. A "longitudinally extending projection" is a relatively long projection, skirt, or appendage which extends downwardly from an elastomeric wall used in this invention into the bore portion.

Furthermore, another advantage of the claimed, elastomeric wall of this invention is as indicated in the first complete paragraph of specification page 11; i.e., such relatively flat elastomeric walls "... can be mass produced from appropriate elastomer sheeting by a process of punching out the disks of elastomer 20a, for a significant saving of manufacturing costs over molded, elastomeric walls."

Extruded elastomer sheeting may be used in those circumstances where the elastomeric wall is quite flat, although small projections or other profiled surface may be stamped or rolled into such sheeting.

By way of explanation, turning to the language on page 11 quoted above: "... such an elastomeric wall is wider than it is long ..." This is from the perspective of the axis of the tubular structure 16 (Fig. 1a, for example) on which it rests. The length of elastomeric wall 20 is in the direction of the axis of structure 16, and its width is perpendicular thereto.

It should also be pointed out that while a disk shape is specifically disclosed for the elastomeric wall, walls of rectangular shape or the like might well be used.

Accordingly, it is believed that claims 1 and 9 are in compliance with 35 U.S.C. 112.

The examiner has also rejected claims 1-22 as anticipated by Atkinson et al., U.S. Patent No. 5,501,426.

Atkinson et al. '426 shows a medical coupling site valve body, in which a resealable valve element 16 is formed from an elastomeric material (column 6, line 46). However, the valve element or member 16 also "... includes a tubular body portion 28 extending substantially parallel to the longitudinal axis 20 and defining a first end 30 and a second end 32 wherein the second end 32 is in contact with the support base 12 adjacent to the end wall 26. The valve element 16 further includes a thin flexible diaphragm 34 extending across the first end 30 of the body portion 16." (Column 6, lines 61-67.)

Thus, the valve element 16 of Atkinson et al. is of a cup shape, with the closed diaphragm end 34 of the cup facing outwardly (Fig. 2).

To the contrary, as called for in claims 1 and 9 of this application, the elastomeric wall 20, 20a, etc. used in this invention, and analogous to the flexible diaphragm 34 of Atkinson et al., Fig. 2, is "essentially free of longitudinally inwardly extending projections...." This is as illustrated in Fig. 1a, of this application, for example, by elastomeric wall 20, which is shown to be a disk in the specific embodiment. See also elastomeric walls 20a, 20b, and 20c respectively in Figs. 2, 3 and 4.

Accordingly, there is a clear contrast in the structure of the claims of this application, and the structure as illustrated in Atkinson et al.

Furthermore, there is an advantage in the structure of this invention over that of Atkinson et al., as stated, for example, at page 5, second to last paragraph of the application: "With such a seal being inside of the elastomeric wall, a simplified elastomeric wall can be used without major, extending skirts or other appendages as in much of the prior art, while such an elastomeric wall can be swabbed for aseptic cleaning, and good, reliable sealing and retention between the male luer and the medical device can still be achieved."

The simplification of the elastomeric wall 20 of Figs. 1 and 1a of this application is clear, upon an examination of the corresponding structure in Atkinson, as discussed above. A particular advantage of this improvement is as specified at page 10 of the specification, second complete paragraph: "Elastomeric wall 20 may be a disc of conventional elastomer used for such a purpose, which is cut out of a sheet of the elastomer, for an efficient, mass production method for producing such elastomeric walls 20 at a cost which is substantially cheaper than molding, as may be required for many of the elastomeric, penetrable members used in prior art systems."

Clearly, the elastomeric wall of Atkinson has to be molded. It cannot be cut out of a sheet, which illustrates a significant, cost saving advantage of this invention. In the area of medical injection sites, cost is generally a critical factor.

Thus it is believed that claims 1-22 are patentable over Atkinson et al., U.S. patent 5,501,426.



In view of the above, allowance of the claims is respectfully requested.

Respectfully submitted,

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